

# **EXHIBIT O**

## JONES DAY

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July 13, 2009

### VIA EMAIL

M. Justin Draycott, Esq.  
Patrick Henry Building  
601 D Street, N.W.  
Washington, DC 20004

Re: *United States ex rel. Ven-A-Care of the Florida Keys v. Abbott Laboratories, Inc.*

Dear Justin:

This letter requests proposed dates and identifying information for outstanding depositions related to (1) Abbott's 30(b)(6) topics, (2) depositions at which the Government asserted the deliberative process privilege, and (3) CMS Office of Legislation employee Ira Burney. Because these depositions will likely be cross-noticed in other AWP cases, it is important that we schedule them sufficiently in advance of the actual depositions.

**Outstanding 30(b)(6) Subjects of Inquiry.** As you know, Magistrate Bowler granted Abbott's motion to compel deposition testimony on the following 30(b)(6) topics:

#### Remaining Topics from Abbott's November 21, 2007 Letter

2. CMS's contemporaneous position during 1991-2003 concerning the meaning of AWP in any relevant Medicare or Medicaid statute or regulation, and the manner in which CMS and its carriers interpreted or implemented AWP in accordance with that position, including but not limited to:

- (a) how CMS, its employees, agents, or carriers interpreted and applied the term "AWP" or "national average wholesale price" as used in 42 C.F.R. 405.517;
- (b) how CMS, its employees, agents, or carriers interpreted and applied the term "AWP" or "Average Wholesale Price" as used in Section 4556 of the Balanced Budget Act of 1997, 42 U.S.C. § 1395u;
- (d) whether CMS, its employees, agents, or carriers believed that "[t]he general concept that the AWP refers to the price at which a pharmaceutical firm

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or wholesaler sells a drug to its customers is commonly understood in the industry” (United States’ Objections and Responses to Defendant Abbott’s First Set of Interrogatories at 35 (12/4/2006));

3. The manner in which CMS, its employees, agents, or carriers have interpreted or implemented the term “Average Wholesale Price” or “AWP” since the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Pub. L. 108-173).

7. What steps CMS, its employees, agents, or carriers took upon learning of the Ven-A-Care qui tam complaints, the article published in Barron’s magazine entitled “Hooked on Drugs” (June 10, 1996), or any other communication advising them that AWP’s for the Subject Drugs exceeded the acquisition costs for those drugs.

8. Why CMS, its employees, agents, and carriers, and various state Medicaid programs continued to pay for drugs based on published AWP’s even when presented with evidence that AWP’s did not represent the price at which physicians and pharmacists purchased drugs, including whether the decision to pay for drugs based on AWP in Medicare or any state Medicaid program was affected in any way by

- (a) political negotiations;
- (b) concern about adversely affecting access to care for Medicare and Medicaid beneficiaries; or
- (c) a deliberate effort to “cross subsidize” physicians and pharmacists for inadequate dispensing fees or inadequate payments for services rendered incident to administering infusion or injection drugs.

9. What the Medicare program would have paid for the Subject Drugs had they had actual knowledge of the prices at which physicians and other customers purchased the Subject Drugs.

10. Any communications by CMS, its employees, agents, or carriers, DOJ, or any state Medicaid program to any compendia seeking to prevent, discourage, or alter in any way the publication of AWP data.

16. Any and all efforts by CMS to establish a Federal Upper Limit for any of the Subject Drugs or Subject J-Codes during the Relevant Claim Period, as authorized by 42 C.F.R. § 447.332, and CMS’s reasons for any decision or policy not to establish a FUL for the Subject Drugs and other injectables.

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17. Any and all efforts by CMS to disapprove state Medicaid plan amendments that based payment for drugs on AWP for any of the Subject Drugs or Subject J-Codes during the Relevant Claim Period, and CMS's reasons for any decision or policy not to use its authority to disapprove state Medicaid plan amendments that paid for drugs based on AWP or any formula that did not result in an accurate estimate of acquisition costs.

18. The frequency and manner in which each State Medicaid agency made findings and assurances to CMS during 1991-2003, as required by 42 C.F.R. § 447.333, that "[i]n the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.331 of this subpart," as well as all communications between CMS and State Medicaid agencies regarding these findings and assurances, all related guidance or interpretations provided by CMS, all efforts by CMS during 1991-2003 to request and/or evaluate any "data, mathematical or statistical computations, comparisons, and any other pertinent records to support [the State Medicaid agencies'] findings and assurances" (§ 447.333(c)), or CMS's reasons for any decision not to require states to make such findings and assurances. With respect to multiple source drugs for which CMS did not establish an upper limit under § 447.332, this topic includes the frequency and manner in which each State Medicaid agency made annual findings and assurances to CMS that "[i]n the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.331 of this subpart." 42 C.F.R. § 447.333(b).

22. All efforts taken to preserve evidence in response to the March 17, 2000 request made by various pharmaceutical manufacturers that the government not destroy evidence supporting those manufacturers' defenses in this case. See Ex. E to Abbott's Motion For a Preservation Order and Affidavit Regarding Spoliation Issues (Sept. 13, 2007).

(Dec. 4, 2008 Hrg. at 29-45.) For your convenience, I have attached a copy of the redlined document which was used during the hearing with Magistrate Bowler.

Please provide, at your earliest convenience, the name(s) of the witness(es) who will be prepared to testify regarding each of the above subjects, as well as proposed dates for each of these depositions. It probably makes sense to avoid those weeks where summary judgment briefing is due. We expect that the witness(es) designated for Topic 2 will be prepared to testify regarding the "revised opinion" from OGC counsel referenced in HHD340-0031-0034. Also, we expect that the witness(es) designated for Topics 8, 17, and 18 will be prepared to testimony regarding the document recently produced at HHD327-000001-000004 (the CMS decision memorandum).

**Deliberative Process Privilege Challenges.** The Special Master's June 29, 2009 Supplemental Memorandum and Order on *In Camera* Review of Documents and Deposition

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Testimony granted Abbott's motion to compel testimony on 23 instances where Government counsel asserted the deliberative process privilege to instruct federal employees not to answer deposition questions. The June 29 Order provides that "the particular witnesses should be produced for further interrogatory on the subjects in issue."

Please provide proposed dates for the scheduling of these witnesses (Messrs. Vito, Reed, Niemann, Booth, Tawes, Thompson, and Ms. Ragone). Please coordinate the depositions of Mr. Vito, Mr. Tawes, and Ms. Ragone so that they can be completed in one trip to Philadelphia. Again, it probably makes sense to avoid those weeks where summary judgment briefing is due.

**Ira Burney.** Please provide proposed dates for the deposition of Mr. Burney.

Thank you for your attention to these matters.

Sincerely,

/s David S. Torborg

David S. Torborg

cc: Counsel for Ven-A-Care  
Counsel for Dey  
Counsel for Roxane